American Society of Health-System Pharmacist's Presentation at the Food and Drug Administration's July 26, 2002, Public Meeting on Bar Code Labeling for Drug Products.

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My name is Kasey Thompson, and I am the Director of the Center on Patient Safety of the American Society of Health-System Pharmacists (ASHP). ASHP is the 30,000-member national professional association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care agencies, and other components of health care systems. I am pleased to provide you with ASHP's views on the proposal to require that pharmaceutical manufacturers include bar coding on drug products.

Before I address the questions that the FDA asked in its announcement of this meeting, I would like to draw the FDA's attention to one point: ***Bar coding technology is entrenched throughout America in all types of venues -- grocery stores, department stores, libraries. It's something everyone expects and it's found everywhere, except where it can do the greatest good -- saving lives.*** This is a high urgency, public health and safety issue. ***The time for action is now.***

ASHP has long supported the use of such technology to help prevent patient harm resulting from medication errors. In a policy adopted in 1999, ASHP supported the application of machine-readable codes to improve patient safety in health systems and specified that the Society would "advocate that all drug product packaging include a machine-readable code in a manner that identifies the package contents, including NDC, lot numbers, and expiration dates." In 2001, ASHP adopted a more specific policy to "urge the Food and Drug Administration to mandate that standardized machine-readable coding be placed on all manufacturers' single-unit drug packaging to (1) ensure the accuracy of medication administration, (2) improve efficiencies within the medication-use process, and (3) improve overall public health and patient safety."

On July 10, 2001, ASHP wrote to Secretary of Health and Human Services Tommy G. Thompson, urging him, through the authority of the FDA, to develop regulations that mandate that drug manufacturers provide a standardized machine-readable code (bar coding) on all drug product containers, including single unit containers. ASHP's

rationale for this request was that drug manufacturers have an obligation, in the interest of patient safety, to provide bar coding for drug products.

This is not a new concept. We know that the FDA has heard this recommendation over and over again. In January 1998, the agency held a workshop at the National Institutes of Health entitled "Minimizing Medical Product Errors: A Systems Approach." At that meeting, Dr. Lucian Leape of the Harvard School of Public Health stated that drug manufacturers should make high leverage changes prior to marketing a product, including providing medications in unit dose packages and bar-coding their products. **That was more than four and a half years ago!**

The 1999 Institute of Medicine (IOM) report, "To Err is Human: Building a Safer Health Care System," notes that bar coding "is an effective remedy" for medication errors, "a simple way to ensure that the identity and dose of the drug are as prescribed, that it is being given to the right patient, and that all of the steps in the dispensing and administration processes are checked for timeliness and accuracy."

The February 2000 report prepared by the Quality Interagency Coordination (QuIC) Task Force in response to the IOM report noted the advances made in medication safety by the Department of Veterans Affairs. That report described the use of bar coding technology and concluded: "bar-coding of medications and use of robotics in dispensing medications can ensure that the appropriate medication is provided to the appropriate patient at the appropriate time." The FDA was represented on the QuIC Task Force.

Finally, last December, the FDA announced in its semiannual agenda that it would publish a proposed rule requiring bar coding on drug and biological products. The agency stated that the purpose behind the proposal was to "help reduce the number of medication errors." This was so important a step toward improving patient safety that DHHS Assistant Secretary Bobby P. Jindal personally announced it at ASHP's Midyear Clinical Meeting in New Orleans on the day that the notice appeared in the *Federal Register*. ASHP welcomed the FDA's announcement, and supports its stated purpose.

But again, time is slipping by. The December 3 announcement of the coming regulation indicated that the FDA hoped to have it available in April. Then we heard that it would be delayed until this summer. The most recent agency semi-annual agenda says that he proposed rule would be issued in November. ASHP has criticized the FDA in the past for dragging its feet on necessary changes in drug product packaging to assure patient safety. It may not be necessary to repeat such criticism, but ***the need for this step is great, and the time for it is long overdue.***

The FDA also recognized in its December 3 announcement what health professionals have long been telling the agency: that "if a health professional could use a bar code scanner to compare the bar code on a human drug product to a specific patient's drug regimen, the health professional would be able to verify that the patient is receiving the right drug, at the right dose, and at the right time."

ASHP has the following specific comments related to the questions the FDA asked in the *Federal Register* notice announcing the July 26 public hearing:

General Questions Related to Drugs and Biologics:

1. Which medical products should carry a bar code? What about blood products and vaccines?

   Bar codes should be required on all pharmaceutical product packages ***down to the unit-dose – single unit level.*** This should include prescription and over-the-counter medications, as well as vaccines and blood products. For bar coding to be effective in hospitals and health systems, products in unit-dose packages ***must*** be made available by pharmaceutical manufacturers. While we have received reports that some major pharmaceutical manufacturers are about to make a public commitment to add bar coding to all packaging, including unit-dose, some of our members report a disturbing trend whereby fewer and fewer pharmaceutical manufacturers are producing products in unit-dose, leaving repackaging up to individual hospitals. This is a major concern of ASHP. Not only does repacking introduce new opportunities for mistakes to be made, it adds an additional cost, which most average- to small-size hospitals cannot afford. Repacking also takes pharmacists away from their most important duty in hospitals – *managing patients' drug therapy.* There is evidence from over 40 years of research on the subject that proves that unit-dose drug distribution systems improve patient safety by reducing medication errors, are more efficient, and are more cost effective than other systems. In this week's *Journal of the American Medical Association,* Lucian Leape, Donald Berwick, and David Bates write that "the unrealized potential of this practice [unit dosing] alone for reducing injury probably far exceeds that of most of the other 72 items on the list" of patient safety practices in a 2001 evidence report prepared for the Agency for Healthcare Research and Quality.

   In the interest of enhancing patient safety, ASHP advocates for the inclusion of bar codes on all pharmaceutical product packages, and for pharmaceutical manufacturers to make all products available in unit-dose form.

2. What information should be contained in the bar code that is critical to reducing medical product errors?

   Bar codes on drug products *must* contain the product's NDC number. This is the primary element that will be effective in meeting the FDA's expectation, as noted in the agency's semi-annual agenda on December 3, 2001, that "if a health professional could use a bar code scanner to

compare the bar code on a human drug product to a specific patient's drug regimen, the health professional would be able to verify that the patient is receiving the right drug, at the right dose, and at the right time."

Other elements that should be mandated include: (1) a product's lot number, which can identify products for the purpose of a drug recall. A database can link a specific lot given to a specific patient. Inclusion of the lot number would also be useful during public health crises where mass vaccinations or drug treatments need to be given. (2) a product's expiration date. Drugs are kept in numerous places throughout hospitals, and even with the diligent efforts of pharmacists and technicians to check for out-of-date products, it is impossible to verify (and find) them all. Placing the expiration date on the bar code would tell nurses at a patient's bedside if a drug were out-of-date – ***before*** the drug is given to the patient.

3. Should the proposed regulation adopt a specific bar code symbology?

Numerous symbologies exist for machine-readable coding of products, but some are receiving more attention than others because of their ability to fit on small package sizes and readability by most commercially available scanners. Common information system standards need to be developed -- either by FDA mandate in the proposed regulation or through collaboration between industry, health-care professionals, and technology experts – and consistently applied for bar code systems to effectively interface with other hospital computer systems such as pharmacy, laboratory, blood bank, and billing systems.

4. Where on the package of drug products should the bar codes be placed?

The bar code should appear on both the inner and outer wrap, below the human-readable information. Bar codes on outer wraps are useful for inventory and distribution control. Bar codes on inner packaging are imperative at the time of drug administration. Experts in the pharmaceutical industry are most qualified to decide where on the package a bar code can most reliably be scanned to prevent scan failures.

5. What products already contain bar codes, who uses the bar codes, and how?

Reliable data does not exist on how many current products packaged in unit-dose form contain bar codes, but it is well-recognized that that number is few, especially for unit-dose packages containing a standard bar code and the necessary data elements of NDC, lot number, and expiration date. The Department of Veterans Affairs is a national leader in using bar coding systems for scanning patient, nurse, and drugs at the bedside. A 1999 ASHP survey revealed that only 1.1 percent of U.S. hospitals use bar coding to scan patient, nurse, and drug at the bedside. We are all aware

however, of mounting public pressure to improve patient safety. Once drug product packaging has bar codes, the pressure to improve safety by applying bar coding technology in institutional settings will escalate. Institutions need incentives to use this important patient safety enhancing technology. This can be achieved through an FDA requirement and a commitment by manufacturers to do what's right for patients – include bar codes on all product packages, and make all products available in unit-dose form.

General Questions and Economic Impact Questions:

6. What is the expected rate of acceptance of machine-readable technologies in health-care sectors: What are the benefits of using this technology in delivering health care services and other potential uses?

Practitioner demand for bar codes on prescription drug products, and the capability of implementing such technology exist. More hospitals and health systems are in various stages of adopting machine-readable systems. What is needed is the product packaging that would allow its use. The benefits of using machine-readable coding in health care sectors are two-fold:

1. First and foremost, a bar coding system will improve patient safety. Scanning medications against an original, pharmacist-verified order before a drug leaves the pharmacy as well as scanning patient and unit-dose medication at a patient's bedside will help ensure that the right patient gets the right dose of the right drug by the right route and at the right time.

2. Second, a properly designed and implemented bar code system will enhance the efficiency and workflow of pharmacists, nurses, and other health professionals using the technology. A code system will be useful in bedside scanning, inventory control, billing, and laboratory systems.

7. When should a final rule requiring bar coding on drug products become effective?

We hope that there will be no more delays in an FDA requirement and a commitment by manufacturers to do what's right for patients. Considering the number of years this proposal has been discussed with no clear action having been taken, an early effective date is necessary. We are afraid, however, that from the continual hesitation to take action on this issue, we will not see anything from the FDA soon. If a proposed rule is not issued until this fall, even with a short public comment period, it will probably be at least a year from now until we see the agency's final rule. How much time will then be given to manufacturers to make the

necessary changes – a year or two? Market demand by end users – hospitals, healthcare practitioners, wholesalers, and patients – can help drive the speed at which drug manufacturers implement the new regulation.

ASHP appreciates the opportunity to comment to the FDA on this significant issue. We are ready to assist the agency in any way in developing its proposed and final regulations requiring bar coding on drug and biological products.